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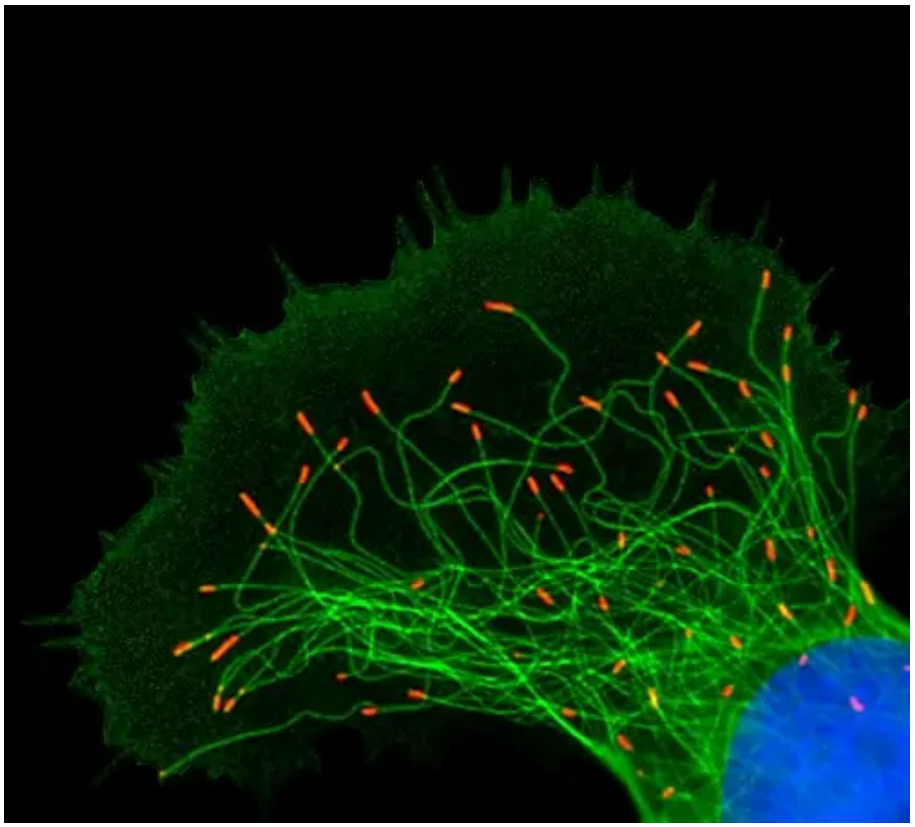
Onco-this-Week

November 11, 2018(https://sciwri.club/archives/date/2018/11/11)



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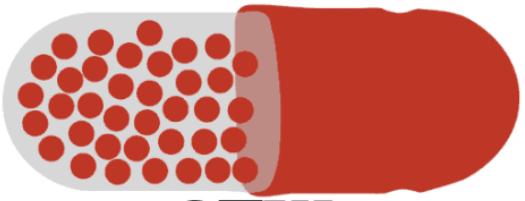
In Onco-this-Week, FDA announces the approval of elotuzumab (Empliciti®) with pomalidomide and dexamethasone targeting of relapsed or refractory #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) in patients, alongside another approval of pembrolizumab (Keytruda) for patients with advanced hepatoceullar carcinoma pre-treated with sorafenib. Lixte Biotechnology's IND receives approval from FDA to conduct a phase 1b/2 Trial of LB-100 in patients with Myelodysplastic Syndrome at Moffitt Cancer Center. ADCETRIS® (Brentuximab Vedotin) is submitted for supplemental biologics license application by Seattle Genetics for frontline treatment of CD30-Expressing Peripheral T-Cell Lymphomas. Check out even more oncology news from the pharmaceutical industry and a trivia on the different kinds of Clinical Trials in this edition of Onco-this-Week by Richa Tewari.- Abhi Dey (https://www.linkedin.com/in/abhinavdey/)



OTW in a Capsule

1. ***Pembrolizumab's accelerated approval in Sorafenib-treated HCC patients.*** Despite recent therapeutic advancements in HCC, for advanced recurrent patients, there are still very few treatment options (including Nivolumab's approval last year). Thus Pembrolizumab's accelerated approval from Ph II trial comes as encouraging news to patients who progress on Sorafenib. The approval marks 14th indication for Pembrolizumab and is based on DoR and ORR data. The approval would be continued if the clinical benefit is continued in confirmatory trial.

2. ***Initiation of registrational trial of farnesyl transferase inhibitor Tipifarnib in HRAS m+ SCCHN patients.*** Kura Oncology's presentation of updated preliminary results from Ph II clinical trial in ESMO 2018 generated a strong buzz around the clinical benefit observed in HRAS mutant SCCHN patients, a population with high unmet need. Initiation of a registrational trial is thus unsurprising for most physicians and analysts; however it would be interesting to see if Tipifarnib can outdo other treatment options (Pembrolizumab, Nivolumab and Cetuximab) in Ph III trial.

3. ***FDA approval of Elotuzumab + pomalidomide + dexamethasone (EPd) in R/R MM patients.*** EPd becomes the first triplet combination approved based on a head-to-head comparison with standard of care pomalidomide + dexamethasone. The combination was granted a priority review by the FDA in late August. This approval maintains the prominence of Elotuzumab in relapsed/refractory settings, which started way back in 2015 when a combination of elotuzumab with lenalidomide and dexamethasone scored an approval in FDA, followed by EU.

(https://goo.gl/VLv3K1)

DRUG APPROVALS

Elotuzumab+ pomalidomide + Low-Dose Dexamethasone in R/R MM patients approved in US based on Ph II ELOQUENT-3 trial data (https://news.bms.com/press-release/bristolmyers/us-food-and-drug-administration-approves-empliciti-elotuzumab-plus-pomali)

> The #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) announced the approval of elotuzumab (Empliciti®) by intravenous injection in combination with pomalidomide and dexamethasone (EPd) for treatment of relapsed or refractory #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) in patients... https://t.co/FTjRgluEL5 (https://t.co/FTjRgluEL5) pic.twitter.com/M9C705WphJ (https://t.co/M9C705WphJ)
>
> — IMF – Myeloma.org (@IMFmyeloma) November 9, 2018 (https://twitter.com/IMFmyeloma/status/1060946134649200640?ref_src=twsrc%5Etfw)

"Empliciti plus pomalidomide and dexamethasone has been proven to extend the time that certain patients live without disease progression, giving health care professionals an effective new tool to tackle this relentless cancer," said Joseph E. Eid, M.D., senior vice president and head of Medical, Bristol-Myers Squibb. "Today's approval reinforces the importance of Immuno-Oncology in blood cancers and expands the role of Empliciti to address the needs of relapsed or refractory multiple myeloma patients."

Pembrolizumab granted accelerated approval in Sorafenib-treated HCC patients based on Ph II KEYNOTE-224 data (https://www.mrknewsroom.com/news-release/research-and-development-news/fda-approves-mercks-keytruda-pembrolizumab-treatment-pati)

"Hepatocellular carcinoma is the most common type of liver cancer in adults, and while we have seen recent therapeutic advancements, there are still limited treatment options for advanced recurrent disease," said Dr. Andrew X. Zhu, lead investigator and director of liver cancer research at Massachusetts General Hospital and professor of medicine at Harvard Medical School. "Today's approval of KEYTRUDA is important, as it provides a new treatment option for patients with hepatocellular carcinoma who have been previously treated with sorafenib."

> The FDA approved pembrolizumab (Keytruda) for patients with advanced hepatocullar carcinoma and who hav already been treated with sorafenib. https://t.co/jQxI3MNoZH (https://t.co/jQxI3MNoZH) #HCC (https://twitter.com/hashtag/HCC?src=hash&ref_src=twsrc%5Etfw) #LiverCancer (https://twitter.com/hashtag/LiverCancer?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer Research Institute (@CancerResearch) November 11, 2018 (https://twitter.com/CancerResearch/status/1061627211436957696?ref_src=twsrc%5Etfw)

“The approval of KEYTRUDA for advanced hepatocellular carcinoma marks the second FDA approval for hepatocellular carcinoma in Merck’s oncology portfolio this year, underscoring our commitment to help bring forward new treatment options for cancers that have historically been very challenging to treat,” said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. “We look forward to continuing to advance research for hepatocellular carcinoma across our portfolio with the goal to help even more patients affected by this type of cancer.”

SPECIAL STATUSES

Selinexor receives Fast track designation for R/R DLBCL patients (http://investors.karyopharm.com/news-releases/news-release-details/karyopharms-selinexor-receives-fast-track-designation-fda-0)

“The receipt of Fast Track designation from the FDA for selinexor in relapsed DLBCL underscores the great unmet medical need for this aggressive form of lymphoma,” said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. “Pending positive results from the Phase 2b SADAL study, we plan to submit a second NDA to the FDA in the first half of 2019, with a request for accelerated approval, for oral selinexor as a potential new treatment for patients with relapsed or refractory DLBCL.”

> Selinexor mechanism of action: it is an oral drug that inhibits XPO1 exportin (a nucleocytoplasmic transport receptor placed in the nuclear membrane responsible for transporting most of the tumor supressors – like p53 – out of the nucleus) pic.twitter.com/Z5be1uZiPc (https://t.co/Z5be1uZiPc)
>
> — Lucas Cantadori (@_Rasga_) November 6, 2018 (https://twitter.com/_Rasga_/status/1059849899674603520?ref_src=twsrc%5Etfw)

REGULATORY NEWS

IND of LB-100 approved to conduct a Ph Ib/II trial in low and intermediate-1 risk MDS patients (http://globenewswire.com/news-release/2018/11/05/1645399/0/en/FDA-Approves-Lixte-Biotechnology-s-IND-to-Conduct-a-Phase-1b-2-Trial-of-LB-100-in-Patients-with-Myelodysplastic-Syndrome-at-Moffitt-Cancer-Center.html?ev=1)

> Lixte Biotechnology Holdings, Inc. (LIXT: OTCQB) | FDA Approves Lixte Biotechnology’s IND to Conduct a Phase 1b/2 Trial of LB-100 in Patients with Myelodysplastic Syndrome at Moffitt Cancer Center https://t.co/ZgcmREQt7g (https://t.co/ZgcmREQt7g)
>
> — Brett Goetschius (@growthcaplist) November 5, 2018 (https://twitter.com/growthcaplist/status/1059511868430135297?ref_src=twsrc%5Etfw)

Dr. John S. Kovach, founder and CEO of Lixte, said, “We are very pleased to receive approval to proceed with a study of the potential benefit of our lead protein phosphatase 2A inhibitor, LB-100, in the treatment of refractory MDS to be conducted by the team at Moffitt, long-time leaders in this field. Low and intermediate-1 risk MDS are often characterized by failure to produce normal amounts of red blood cells, so that patients with this syndrome require frequent blood transfusions. Reduction in the number of transfusions needed by these patients is one major goal of therapy, and provides a readily assessable parameter of therapeutic benefit within a few months of initiating treatment. At present, there is only one drug, Revlimid (Celgene), approved for one subtype of MDS.”

sBLA submitted for CD30-targeting ADC Brentuximab vedotin in 1L CD30+ PTCL patients (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-submits-supplemental-biologics-license-1)

> Seattle Genetics Submits Supplemental Biologics License Application for ADCETRIS® (Brentuximab Vedotin) in Frontline Treatment of CD30-Expressing Peripheral T-Cell Lymphomas https://t.co/Lx1a3LiTA4 (https://t.co/Lx1a3LiTA4) pic.twitter.com/DYtOxwG12a (https://t.co/DYtOxwG12a)
>
> — Latest News from Business Wire (@NewsFromBW) November 5, 2018 (https://twitter.com/NewsFromBW/status/1059430913010876416?ref_src=twsrc%5Etfw)

"CD30 is expressed in several subtypes of peripheral T-cell lymphoma, an aggressive type of non-Hodgkin lymphoma, and the current standard of care for frontline treatment consisting of a multi-agent chemotherapy regimen called CHOP has not changed in several decades," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "Results from the ECHELON-2 trial demonstrated a statistically significant and clinically meaningful improvement in progression-free survival and importantly, overall survival, in patients with previously untreated CD30-expressing PTCL who were treated with ADCETRIS in combination with CHP chemotherapy over standard of care CHOP chemotherapy. We believe these superior results over standard of care represent a significant advance for patients with CD30-expressing PTCL and for the medical community, and we look forward to working with the FDA during the review process of this application to bring this potential new treatment regimen to patients as quickly as possible."

EMA validates and grants accelerated assessment of MAA for FLT3 Inhibitor Quizartinib in R/R FLT3-ITD+ AML patients on the basis of Ph III QuANTUM-R trial (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006926.html)

> European Medicines Agency Validates and Grants Accelerated Assessment for Quizartinib in AML – Onco'Zine https://t.co/zt1CVL3FIL (https://t.co/zt1CVL3FIL)
>
> — Onco'Zine – Network (@OncoZine) November 10, 2018 (https://twitter.com/OncoZine/status/1061140285780983808?ref_src=twsrc%5Etfw)

"The accelerated assessment of the quizartinib MAA underscores the significant unmet need for patients with relapsed/refractory FLT3-ITD AML, a very aggressive form of the disease with no approved targeted treatment options in Europe," said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. "Achieving both these milestones are significant next steps and we look forward to working with the EMA to bring this important potential new targeted treatment option to patients in the EU."

TRIAL RESULTS

Azacitidine + nivolumab combination results in complete remission for 22% R/R AML patients in Ph II trial (https://www.mdanderson.org/newsroom/2018/11/combination-chemotherapy-and-immunotherapy-effective-in-phase-2-leukemia-study.html)

ICYMI: Study led by @Daver_Leukemia (https://twitter.com/Daver_Leukemia?ref_src=twsrc%5Etfw) found combination of azacitidine and nivolumab resulted in complete remission for 22% of patients with relapsed/refractor #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw): https://t.co/mQt31VLHcR (https://t.co/mQt31VLHcR) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #CancerMoonshot (https://twitter.com/hashtag/CancerMoonshot?src=hash&ref_src=twsrc%5Etfw) #endcancer (https://twitter.com/hashtag/endcancer?src=hash&ref_src=twsrc%5Etfw)

— MD Anderson Cancer Center (@MDAndersonNews) November 11, 2018 (https://twitter.com/MDAndersonNews/status/1061448428595634181?ref_src=twsrc%5Etfw)

"In addition, bone marrow samples taken prior to treatment indicated a higher frequency of pre-therapy bone marrow CD3 and CD8 cells predicted for response to therapy," said Daver. "In particular, CD3 appeared to have a high sensitivity and specificity rate for predicting response, indicating it might serve as a reliable biomarker for selecting patients for this combination therapy."

Ph III TIVO-3 trial of VEGF TKI Tivozanib meets primary endpoint of PFS improvement in 3L-4L RCC patients (https://www.aveooncology.com/wp-content/uploads/2018/11/AVEO-TIVO-3-Topline.pdf)

"Tivozanib's therapeutic profile is distinct among VEGF TKIs as a treatment for RCC, with the TIVO-3 trial demonstrating a significant PFS benefit and a favorable tolerability profile," said Brian Rini, MD, Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Director, Cleveland Clinic Genitourinary Cancer Program, and principal investigator of the TIVO-3 trial. "In the advanced disease setting, these outcomes are particularly meaningful, providing the first large, pivotal dataset that shows sequencing of treatment following earlier TKI and immunotherapy treatment. This profile suggests an important place for tivozanib in the evolving treatment paradigm for RCC and, taken together with early combination data, the need to study tivozanib further in combination with immunotherapies."

AVEO Oncology Announces Phase 3 TIVO3 Trial of Tivozanib in Renal Cell Carcinoma Meets Primary Endpoint: First and Only Positive Phase 3 Study in Third and FourthLine RCC Primary Endpoint Shows 44 Improvement in Median PFS and 26 Reduction in Risk of... https://t.co/vdzU2XloP3 (https://t.co/vdzU2XloP3) pic.twitter.com/BKRG8JzHlk (https://t.co/BKRG8JzHlk)

— Clinical Trials News (@ClinicalPhase) November 5, 2018 (https://twitter.com/ClinicalPhase/status/1059560664660733952?ref_src=twsrc%5Etfw)

"Our determination to fight for tivozanib in 2015, when AVEO faced an important strategic crossroads, came from our belief that it could have a meaningful impact not just on how a disease was treated, but also what the patient experiences through that treatment. Today's outcome is the culmination of that multi-year effort, and a first step in our goal to improve both outcomes and patient experience," said Michael Bailey, president and chief executive officer of AVEO. "We owe our deepest gratitude to the healthcare professionals, many of whom long believed in the potential of tivozanib, and to the patients and their families for participating in our pivotal studies."

TRIAL STATUSES

Ph II SHERBOC study in metastatic breast cancer patients terminated too (http://investors.merrimack.com/

news-releases/news-release-details/merrimack-reports-third-quarter-2018-financial-results-and)

> We're currently enrolling patients with heregulin positive metastatic breast cancer in the SHERBOC study, our Phase 2 clinical trial of MM-121, a monoclonal antibody targeting HER3. Learn more: https://t.co/XLclfhLiXg (https://t.co/XLclfhLiXg)
>
> — Merrimack (@MerrimackPharma) July 12, 2018 (https://twitter.com/MerrimackPharma/status/1017468986609430528?ref_src=twsrc%5Etfw)

"Following a comprehensive review of our drug candidate pipeline, we have determined that a corporate restructuring provides the best path forward to reduce operational costs and maximize value. Naturally, this step was the result of an extremely difficult decision and we regret its impact on the affected members of our team, to whom we remain grateful for their contributions to Merrimack," said Richard Peters, M.D., Ph.D., President and Chief Executive Officer. "Going forward, we remain committed to the efficient development of targeted therapies for biomarker-defined cancers, as we are now focused on our clinical development program for MM-310, for which we anticipate providing another safety update in Q1 2019, and our emerging preclinical candidates, MM-401 and MM-201."

First patient dosed in Ph II KEYNOTE-890 trial of Pembrolizumab + TAVO in late stage 2L+ TNBC patients (https://ir.oncosec.com/press-releases/detail/1967/oncosec-doses-first-patient-in-keynote-890-phase-2-clinical)

> OncoSec Initiates KEYNOTE-890, a Phase 2 Clinical Trial of TAVO in Combination with Merck's KEYTRUDA® (pembrolizumab) for the Treatment of Late-Stage Triple Negative Breast Cancer https://t.co/7KB8uML6Ef (https://t.co/7KB8uML6Ef)
>
> — NGT Consulting (@natGeneTherapy) October 16, 2018 (https://twitter.com/natGeneTherapy/status/1052217988601012227?ref_src=twsrc%5Etfw)

"Treating the first patient in our KEYNOTE-890 clinical trial is an important milestone for OncoSec as we seek to rapidly advance this program," said Kellie Malloy Foerter, Chief Clinical Development Officer of OncoSec. "Additionally, this study is important for patients with metastatic triple negative breast cancer given the lack of treatment options currently available. Prior clinical observations suggest that TAVO™ in combination with pembrolizumab is a valid therapeutic approach for TNBC. Based on the outcome of the study and feedback from FDA, we may choose to expand the study and seek accelerated approval with the FDA for this patient population."

Registrational trial of farnesyl transferase inhibitor Tipifarnib initiated in HRAS m+ HNSCC patients (http://ir.kuraoncology.com/news-releases/news-release-details/kura-oncology-initiates-registration-directed-trial-tipifarnib)

Kura's latest news from #ESMO18 (https://twitter.com/hashtag/ESMO18?src=hash&ref_src=twsrc%5Etfw): Updated data from a Phase 2 trial of tipifarnib in patients with HRAS mutant squamous cell carcinomas. https://t.co/fxI1biMVdN (https://t.co/fxI1biMVdN) #PrecisionMedicine (https://twitter.com/hashtag/PrecisionMedicine?src=hash&ref_src=twsrc%5Etfw) @myESMO (https://twitter.com/myESMO?ref_src=twsrc%5Etfw) pic.twitter.com/WG2v2RuMGm (https://t.co/WG2v2RuMGm)

— Kura Oncology (@kuraoncology) October 22, 2018 (https://twitter.com/kuraoncology/status/1054355530142015488?ref_src=twsrc%5Etfw)

"We are excited to announce that our first registration-directed trial is now underway," said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. "Prior to our experience, tipifarnib was studied in more than 5,000 patients and although it demonstrated compelling anti-cancer activity in some cases, no molecular target was identified that could explain such activity. This registration-directed trial implements the many learnings from our clinical experience in patients with HNSCC. We believe we can now identify those patients most likely to receive clinical benefit from tipifarnib. If successful, we believe this registration-directed trial could bring a much-needed treatment option to patients with HRAS mutant HNSCC."

COLLABORATIONS

Nektar and Pfizer to evaluate CD122-biased agonist, NKTR-214 + Avelumab and Talazoparib or Enzalutamide in mCRPC, SCCHN and other cancers (https://ir.nektar.com/news-releases/news-release-details/new-clinical-oncology-collaboration-between-nektar-and-pfizer)

Pfizer's PARP, androgen inhibitors next combo partners for NKTR-214: Pfizer Inc. (NYSE:PFE) will combine NKTR-214 from Nektar Therapeutics Inc. (NASDAQ:NKTR) with the pharma's marketed drugs Xtandi enzalutamide, Talzenna talazoparib and Bavencio avelumab... https://t.co/TPafwB8Qju (https://t.co/TPafwB8Qju)

— cafepharma (@cafepharma) November 6, 2018 (https://twitter.com/cafepharma/status/1059859858688602113?ref_src=twsrc%5Etfw)

"We are excited to partner with Pfizer to evaluate the potential benefit of the combination of NKTR-214 with agents targeting multiple mechanisms in the Company's portfolio for patients with a diagnosis of prostate and head and neck cancer," said Mary Tagliaferri, M.D., Chief Medical Officer and Senior Vice President of Clinical Development at Nektar. "Importantly, this new clinical collaboration will allow us to understand how we might access multiple immuno-oncology and targeted modalities simultaneously to treat cancer in complementary and novel ways."

"We are looking forward to combining Nektar's unique CD122-biased agonist with a number of agents with distinct mechanisms," said Chris Boshoff, M.D., Ph.D., Senior Vice President of Immuno-Oncology, Early Development and Translational Oncology at Pfizer. "We hope to achieve our goal of improving the care of patients with difficult-to-treat cancers with unique immunotherapy-based regimens."

Immunomedics and AstraZeneca to evaluate combination of Durvalumab and Sacituzumab Govitecan in PD-(L)1 progressed NSCLC patients in Ph II trial (https://www.immunomedics.com/our-company/news-and-events/immunomedics-expands-clinical-collaboration-with-astrazeneca-to-include-metastatic-non-small-cell-lung-

cancer/)

“Sacituzumab govitecan has shown very encouraging single-agent activity in NSCLC patients who have failed multiple lines of therapy. The combination study with durvalumab, together with our internal efforts to further develop sacituzumab govitecan monotherapy, will help us define the best registration strategies in NSCLC within accelerated timelines,” said Dr. Robert Iannone, Head of Research & Development and Chief Medical Officer of Immunomedics.

> Immunomedics Expands Clinical Collaboration With Astrazeneca to Include Metastatic NonSmall Cell Lung Cancer: Phase 2 Platform Study to Evaluate the Combination of ImfinziÂ Durvalumab and Sacituzumab Govitecan in Patients with NonSmall Cell Lung Cancer... https://t.co/UejtqHQcqn (https://t.co/UejtqHQcqn)
>
> — Bio-Alliances News (@BioAlliances) November 7, 2018 (https://twitter.com/BioAlliances/status/1060280744696721408?ref_src=twsrc%5Etfw)

Hesham Abdullah, Head of Immuno-Oncology, Global Medicines Development, AstraZeneca said, “The efficacy, safety and tolerability of durvalumab in NSCLC and the clinical activity of sacituzumab govitecan monotherapy in late-line NSCLC, provide promising rationale for the development of the durvalumab and sacituzumab govitecan combination in the metastatic setting. We are excited about the potential of this combination in second-line NSCLC, which may fill an important unmet medical need for patients who desperately need new treatment options.”

BMS and Infinity Pharmaceuticals to assess efficacy of Nivolumab + PI3Ki IPI-549 in urothelial cancer patients (https://news.bms.com/press-release/rd-news/bristol-myers-squibb-and-infinity-pharmaceuticals-announce-new-clinical-collab)

“The expansion of our relationship with Infinity underscores our efforts to follow the science and support potential novel combination therapies in immuno-oncology for cancer patients with limited treatment options,” said Fouad Namouni, M.D., head of Oncology Development, Bristol-Myers Squibb. “Our goal is to determine whether targeting the tumor microenvironment with IPI-549 will enhance the activity of Opdivo for people with urothelial cancer and potentially in other tumor types where MDSCs suppress the immune response.”

> #Infinity (https://twitter.com/hashtag/Infinity?src=hash&ref_src=twsrc%5Etfw) Reports Clinical and Translational #Data (https://twitter.com/hashtag/Data?src=hash&ref_src=twsrc%5Etfw) from Expansion Cohorts of MARIO-1 Phase 1b Study of IPI-549 in Combination with Opdivo® (#nivolumab (https://twitter.com/hashtag/nivolumab?src=hash&ref_src=twsrc%5Etfw)) at #SITC (https://twitter.com/hashtag/SITC?src=hash&ref_src=twsrc%5Etfw)’s 33rd Annual Meeting https://t.co/LhOt3xYggf (https://t.co/LhOt3xYggf)
>
> — IndustryPRwire (@IndustryPRwire) November 10, 2018 (https://twitter.com/IndustryPRwire/status/1061277326938378240?ref_src=twsrc%5Etfw)

“We are excited to advance the development of IPI-549 further into the checkpoint inhibitor treatment-naïve setting with this randomized study in collaboration with the team at Bristol-Myers Squibb.,” said Dr. Sam Agresta, Chief Medical Officer of Infinity. “There continues to be a significant unmet need for additional treatment options for people living with urothelial cancer, and we are excited to evaluate the potential of this combination.”

SITC 2018 COVERAGE

> SITC is pleased to present scientific highlights from the Nov. 10, 2018, sessions of the 33rd Annual Meeting https://t.co/VLYyspxQ1G (https://t.co/VLYyspxQ1G) #SITC2018 (https://twitter.com/hashtag/SITC2018?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/V5miaGVqGT (https://t.co/V5miaGVqGT)
>
> — SITC (@sitcancer) November 11, 2018 (https://twitter.com/sitcancer/status/1061631401362112512?ref_src=twsrc%5Etfw)

1. Early Ph I results of anti-LAG-3 therapy (MK-4280) and anti-TIGIT therapy (MK-7684) presented (https://www.mrknewsroom.com/news-release/oncology/early-phase-1-data-mercks-oncology-pipeline-investigational-anti-lag-3-therapy)
2. Lenvatinib + Pembrolizumab data in three tumor types presented (https://www.mrknewsroom.com/news-release/oncology-newsroom/new-data-investigational-study-lenvima-lenvatinib-and-keytruda-pembro)
3. Jounce Therapeutics announces reverse translational and biomarker data from ICOS Program (http://ir.jouncetx.com/phoenix.zhtml?c=254289&p=irol-newsArticle&ID=2376614)
4. TESARO announces IO data presentations (http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-immuno-oncology-data-presentations-sitc-2018)
5. MacroGenics presents clinical data (http://ir.macrogenics.com/news-releases/news-release-details/macrogenics-reports-presentation-clinical-data-33rd-annual-sitc)
6. Celyad reports update on CYAD-01 solid tumor clinical program (https://www.celyad.com/en/news/celyad-presents-update-on-cyad-01-solid-tumor-clinical-program-at-the-sitc-33rd-annual-meeting)
7. SELLAS Life Sciences announces additional data showing consistent clinical benefit across HLA Allele subgroups in TNBC patients (https://www.sellaslifesciences.com/investors/news/News-Details/2018/SELLAS-Life-Sciences-Announces-Additional-Data-Showing-Consistent-Clinical-Effect-Across-HLA-Allele-Subgroups-in-Triple-Negative-Breast-Cancer-TNBC-Patients-Treated-with-Nelipepimut-S-Plus)
8. NewLink Genetics reports Ph I data and biomarker data (http://investors.linkp.com/news-releases/news-release-details/newlink-genetics-presents-phase-1-data-supporting-significantly)
9. Encouraging preliminary efficacy and safety results seen with CEA-targeting CAR-T in pancreatic cancer and CRC patients with liver mets (http://investors.sorrentotherapeutics.com/news-releases/news-release-details/sorrento-therapeutics-anti-cea-car-t-demonstrates-significant)
10. Preliminary data from KEYNOTE-695 Ph IIb registrational trial of TAVO + Pembrolizumab in PD-1 progressed metastatic Melanoma patients presented (https://ir.oncosec.com/press-releases/detail/1966/oncosec-reports-preliminary-data-from-keynote-695-phase-2b)
11. Updated Ph II data from the Lifileucel metastatic melanoma trial presented (http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2375545)
12. Corvus Pharmaceuticals presented data on lead programs (http://investor.corvuspharma.com/news-releases/news-release-details/corvus-pharmaceuticals-present-data-lead-programs-european)

OTW Trivia

Q: What are different clinical trial types and designs?

A: The clinical trials may be one of the following types:

- ***Basket Trial:*** Basket trials study the outcome of one drug on at least one mutation in multiple tumors at the same time.
- ***Umbrella Trial:*** Umbrella trials study the outcome of one or more drugs on at least one mutation in one tumor at the same time.
- ***Pathway trials:*** Pathway trials involve multiple tumors with multiple mutations targeted by more than one drugs
- ***Seamless trials:*** Trials which compress traditional phases of trials into one continuous trial through multiple expansion cohort study designs
- ***Molecular Profiling:*** Molecular profiling assesses genetic characteristics and/or biomarkers in a cancer type to identify and create targeted therapies.
- ***Targeted Therapy:*** Targeted therapy uses drugs to identify and attack specific types of cancer cells – this ***targeting*** is intended to spare harm to normal cells, thus having fewer side effects than other types of cancer treatment.
- ***Genomic Profiling***: Genomic profiling reveals knowledge of genetic makeup of a patient or cell type to help develop new ways to diagnose and treat cancer.

Source: https://www.asco.org/research-progress/clinical-trials/clinical-trial-resources/clinical-trial-design-and-methodology

About the Author:


(https://io.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg)

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

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(https://i1.wp.com/www.sciwri.club/wp-content/uploads/2016/06/Self2015.jpg)

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Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. He is currently an Assistant Scientist at Emory University (Atlanta, GA) studying mechanisms of tumor recurrence in kids with brain tumors. As a postdoctoral fellow, he was the recipient of two Young Investigator Awards from Alex Lemonade Stand Foundation (Philadelphia, PA) and Rockland Immunochemicals. His current research has been funded by Northwestern Mutual Foundation (Milwaukee, WI), CURE Childhood Cancer Foundation (Atlanta, GA) and American Association for Cancer Research (AACR). When he is not on the bench you will find him spending time with his family or exploring the world through traveling and blogging.

Image Sources: Wikipedia and Twitter

Cover image: (CellImageLibrary)Fluorescent micrograph of a Xenopus melanophore, showing microtubules (green), microtubule plus ends (red) and nucleus (blue). Honorable Mention, 2011 Olympus BioScapes Digital Imaging Competition®.– Source (http://www.cellimagelibrary.org/images/41628)

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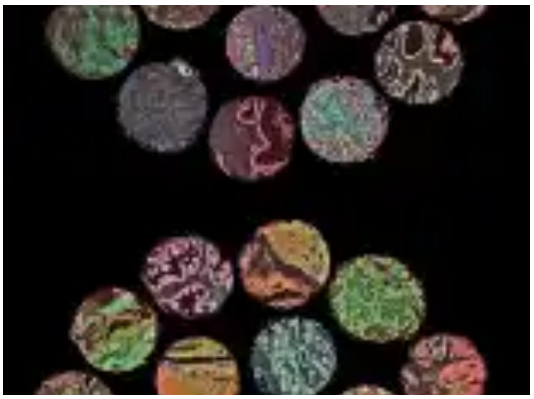

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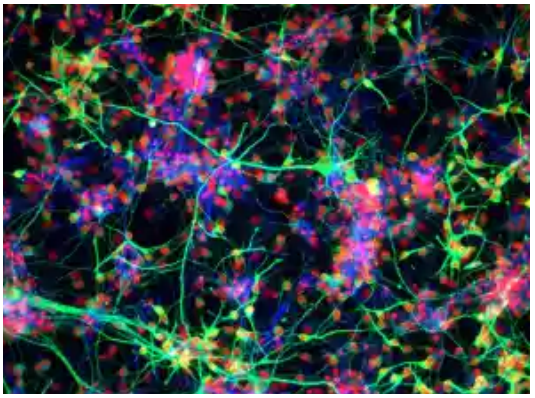

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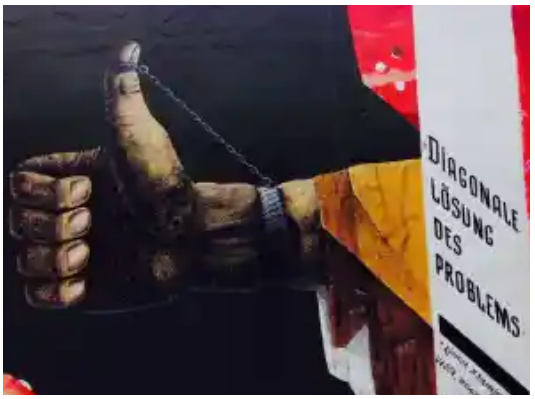

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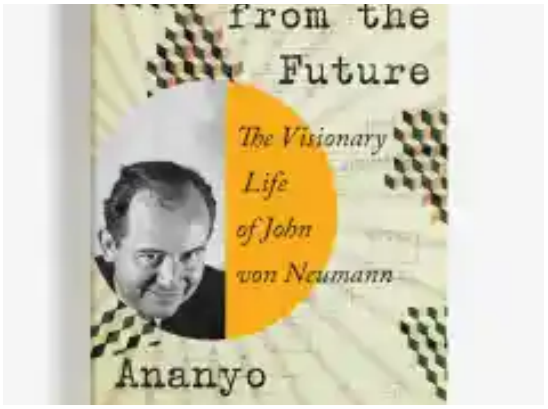

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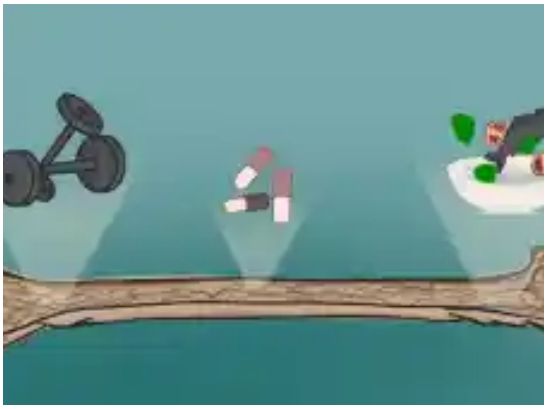

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